DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

August 13, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-59

Robert D. Harrison, President
Earth & Plant, Inc.
P.O. Box 1275
Homer, Alaska 99603

WARNING LETTER

Dear Mr. Harrison:

The Food and Drug Administration (FDA) inspected your firm located at 53135 McNeil Canyon Road, Homer, Alaska, on May 30, 2002. Labeling for your firm's product Hydroxygen Plus indicates serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the food and dietary supplement labeling regulations on the Internet through links on FDA's web page www.fda.gov.

This letter is to advise you of our inspectional findings and the findings of our review of your labeling for the dietary supplement Hydroxygen Plus including your web site www.gethealthyagain.com. Labeling is not limited to the immediate product container but, as defined in Section 201(m) of the Act, includes all promotional material you distribute in connection with your products.

On your web site, under the heading "Natural Immune Support for Lupus," you make the following claims for Hydroxygen Plus.

- "Another benefit of Hydroxygen Plus for lupus is that brain cells get more oxygen since this passes through the blood brain barrier."
- "When you have a low cellular oxygenation condition in the body, as you do with lupus, it makes a lot of sense to take Hydroxygen Plus."
- "I suggest taking supplements that regulate the immune system and strengthen the TH-1 cells that fight infections inside the cells... Directly killing them with Hydroxygen Plus... ."
- "Hydroxygen Plus, taken in therapeutic quantities, can kill a significant amount of mycoplasma and viruses. It could possibly even take care of these lupus causing infections on its own."
- "Hydroxygen Plus: For lupus start taking 3 to 5 drops a day."

- "Hydroxygen Plus is unique among oxygen supplements...when you have a low cellular oxygenation condition in the body, as someone would if they have cancer, it makes sense to take a lot of it."

These statements cause your product to be misbranded under Section 403(a)(1) of the Act. The available scientific evidence does not support the claims you are making for this product. The statements are, therefore, false or misleading and their use in labeling misbrands the product.

These statements also cause your product to be a drug as defined in Section 201(g)(1)(B) of the Act. Because we are unaware of any evidence that this product is generally recognized as safe and effective when used as labeled, it also is a new drug under Section 201(p) of the Act. Under Section 505 of the Act, a new drug may not be legally marketed in the United States without an approved New Drug Application.

The product is further misbranded under Section 502(f)(1) of the Act, in that it fails to bear adequate directions for use, and under Section 502(a) of the Act, in that the labeling is false and misleading because it suggests that the product is effective for its intended use. Efficacy for your product has not been established.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. Other violations can subject the product to legal action. We note there are other labeling violations with other products that we have not included in this letter. It is your responsibility to assure that all of your products are labeled in compliance with the Act and regulations enforced by FDA.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement actions without further notice. These actions include seizure and/or obtaining a court injunction against further marketing of your products.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state the time at which corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Charles M. Breen
District Director